NON-TECHNICAL ABSTRACT

TITLE: Phase I Study of Percutaneous Injections of Wild-Type Adeno-Virus p53 Construct (ADENO-p53) for Hepatocellular Carcinoma (UPCI #96-035).

Enrollment on this study is open to patients with inoperable cancer of the liver. Participation in this study involves treatment with a new investigational agent called Adeno-p53. Adeno-p53 is a new form of treatment for cancer called "gene therapy." A gene is a microscopic unit of heredity in which human traits are passed on in persons. Several types of cancerous tumors, including tumors of the liver, contain an abnormal gene called "mutant p-53." The agent Adeno-p53 is actually a virus changed or altered to carry the normal p-53 gene. When placed into the tumor the normal p-53 gene makes it difficult for the tumor cells to reproduce and spread. The combination Adeno-p53 treatment is an experimental therapy and as such it is not known whether patients will directly benefit from participation in this study.

Approximately 30 patients will participate in this study at the University of Pittsburgh Cancer Institute.

The purpose of this study is to decide the maximum tolerated dose of Adeno-p53 when injected through the skin (percutaneous injection) and directly into a tumor on the liver. The effectiveness and safety of Adeno-p53 in treating cancer of the liver will also be looked at.

Once patients are determined to be eligible for the study, they will be assigned to 1 of 5 different dosage levels. The assignment and dosage amount of the agent Adeno-p53 that each patient will receive depends on when they enter the study and how many patients have been placed on the study before them.

Patients will receive a single injection of Adeno-p53 every 4 weeks as long as it is found that their disease has not gotten worse. Each tumor being treated will be treated with a maximum of six injections of Adeno-p53. Before each injection of Adeno-p53 a CAT scan will be done. Also, at the time of each injection of Adeno-p53, a core biopsy (removal of a small amount of tissue using a needle) of the tumor will be obtained.

After injection of the Adeno-p53, patients will be isolated and observed for approximately 20 hours. They may be asked to remain isolated (away from other people) for up to a week. The reason for this isolation is that there is a possibility that the virus could become active and they would be able to give it to other people like passing on a cold. Sputum (liquid in the mouth) will be checked to see if the virus is able to be passed to others before patients will be able to have any visitors. Isolation times may change depending on the above test.